



WEEK ENDING OCTOBER 10, 2014

# OPP Weekly Activity Report

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## PESTICIDE RE-EVALUATION DIVISION

### **Meeting with Thiamethoxam Registrant to Discuss Registration Review Data Call-In (DCI) Requirements.**

On Monday, October 6, 2014, at the request of OPP, members of PRD and EFED met with representatives from Syngenta to discuss thiamethoxam data relative to the on-going honeybee colony feeding study. Syngenta presented [non-finalized] information from the study, and discussed the issue of supplemental feeding as the test colonies begin to make their way into overwintering. The California Department of Pesticide Regulation (CDPR), Canada's Pest Management Regulatory Agency (PMRA), and Syngenta-Canada participated via teleconference. Thiamethoxam is a broad spectrum nitroguanidine insecticide and a member of the neonicotinoid chemical class. As a conventional pesticide, thiamethoxam is registered to control piercing and sucking insects on several agricultural and non-agricultural commodities; turfgrasses and ornamentals; structures (void spaces, cracks, and crevices of buildings, equipment, vehicles, etc.); and indoor and outdoor baits. Final report of colony feeding study is expected in November 2015. Registration review information for thiamethoxam can be found in docket EPA-HQ-OPP-2011-0581 at [www.regulations.gov](http://www.regulations.gov). (Carissa Cyran, 703-347-8781)

**OPP Responds to National Resource Defense Council Petition.** On October 9, 2014, OPP responded to the National Resource Defense Council's November 26, 2007 Petition Requesting Cancellation of Propoxur for Pet Collar Uses, as Supplemented on April 23, 2009 and January 18, 2011. The Natural Resources Defense Council (NRDC) requested that EPA cancel all registrations of the pesticide propoxur for pet collar uses. The Agency denied, as moot, NRDC's request to cancel all registrations of propoxur for pet collars, because EPA has granted the registrants' requests to voluntarily cancel all registrations of propoxur for pet collars. A letter relaying the decision was sent to NRDC's San Francisco office. (Brittany Pruitt, 703-347-0289)

## ANTIMICROBIALS DIVISION

**Azadioxabicyclooctane Final Work Plan Posted to Docket.** The final work plan for the antimicrobial pesticide azadioxabicyclooctane (AZA) (Case 3023) was signed on September 30, 2014 and posted to the docket as part of the registration review process. In the final work plan, the agency outlined the studies needed to support the registration review risk assessments which will be required through a data call-in scheduled to be issued in September 2015. AZA consists of a mixture of three chemicals, each with a unique PC Code, in equilibrium in the product. The final work plan and other documents relevant to the registration review case are located in docket EPA-HQ-OPP-2013-0604 at [www.regulations.gov](http://www.regulations.gov). (Sandra O'Neill, 703-347-0141)

**Tetraacetylenediamine (TAED) Final Work Plan Posted to Docket.** The final work plan for the pesticide Tetraacetylenediamine (TAED) (PC Code 004115) was signed on September 30, 2014 as part of the registration review process. In the final work plan, the agency outlined the studies needed to support the registration review risk assessments which will be required through a data call-in anticipated to be issued in September 2015. Since the issuance of the PWP, BPPD registered products containing TAED for the early season control of bacterial and fungal pathogens on turf grass, golf courses, greenhouses and in nursery or in field-grown rice and strawberries. In addition, tolerance exemptions for TAED (and its metabolite DAED) have been established in or on rice and strawberries. The final work plan and other documents relevant to the registration review case are located in docket EPA-HQ-OPP-2013-0277 at [www.regulations.gov](http://www.regulations.gov). (SanYvette Williams 703-305-7702 and Colin Walsh, 703-0298, BPPD).

**Antimicrobials Division meets with Health Canada.** On Wednesday, October 8, 2014, the Antimicrobials Division's senior staff met with Adam Gibson Director General, Natural and Nonprescription Health Products Directorate, Health Canada. His Directorate covers over-the-counter drugs, disinfectants, and some sanitizers. The meeting was a high level discussion on communications and decisions regarding emerging pathogens and areas where possible collaboration could occur, such as efficacy reviews and devices. As such, future meetings are planned to determine how to collaborate on efficacy reviews and devices. (Joel Wolf, 703-347-0228)

**OPP attends ORD TOXCAST data summit.** On September 29-30th toxicologists from AD and HED attended a summit hosted by ORD on the updated TOXCAST program. ORD, in coordination with outside stakeholders, presented new and exciting research on how to use the massive amounts of chemical data to inform policy and regulatory decisions. A poster session was held with participants from both ORD and academia, discussing how the data in the TOXCAST database can be mined. Additional discussion was held after the main summit to discuss how OPP can help fulfill the vision of TOXCAST and how ORD can make the system more accessible to scientists at OPP. Jonathan Leshin from AD and Elissa Reaves and Liz Mendez from HED attended. [Jonathan Leshin, 703-347-0142]

**OPP Staff Visit Chromated Copper Arsenate (CCA) Wood Treatment Plant.** On October 8, 2014, staff from AD and the OPP front office visited a CCA wood treatment facility in Warsaw, VA during a wood pressure study field test. The purpose of the trip was educational, OPP attendees observed procedures taken on site to gather data for an observational exposure study that is being conducted at various wood pressure treatment facilities in response to the CCA RED. Representatives from Arch Wood Protection and Wood Preservers, Inc. were on site to guide EPA attendees through treating operations involving cylinders,

stock loading, and field test procedures for collecting exposure sampling data. (Sandra O'Neill, 703-347-0141)

**AD Discusses Intermediate Pesticide Products and Treated Articles with Industry.**

On October 9, 2014, AD, OGC and EPA Region 3 met with representatives from the Silver Task Force of North America, American Chemistry Council Biocides Panel, and Microban to discuss an upcoming guidance document on the regulatory requirements of antimicrobial "intermediates" with material preservative use patterns that are used in the production of treated articles. In the meeting, the representatives discussed their understanding of how "intermediates" have been historically regulated and voiced their concerns on potential impacts to their industry. Industry suggested that they may hold a workshop on the manufacture of treated articles to provide OPP background for the guidance document. (Seiichi Murasaki, 703-347-0163).

**AD Meets with Certol to Discuss Proposed Amendments and New Products.**

September 30, 2014, the Antimicrobial staff met with representatives from Certol International and their regulatory agent, Arnold & Porter, LLC, to discuss several proposed amendments to existing products and potential new product applications. Topics covered included efficacy testing and acute toxicity testing/bridging requirements. The company will evaluate the information received during the meeting and communicate with EPA regarding proposed next steps. (Stacey Grigsby, 703-305-6440)

**FIELD & EXTERNAL AFFAIRS DIVISION**

**FEAD Coordinates with NASDARF on Web-based Reporting System for Pesticide Safety Educators.**

CWPB continued work with the National Association of State Departments of Agriculture Research Foundation staff to complete development of a Web-based reporting system to collect information about the activities of Pesticide Safety Education Programs (PSEPs) that receive PRIA funds for pesticide safety education and training activities that support the applicator certification and training (C&T) programs. CWPB staff met with NASDARF on October 2 to review the final draft design of the reporting system and make final edits and revisions prior to initiating beta testing. The new reporting system will collect information on initial certification and recertification training activities, manual and exam development, and development of other training materials or innovative technologies for pesticide safety education. When implemented, it will enable easier electronic reporting of PSEP activities supported by PRIA funds and will enable EPA, states and tribes to easily identify and share new C&T materials and information about the types and amount of training conducted by PSEPs. (Richard Pont, 305-6448)



**FEAD Participates in Region 6 State/Tribal Pre-SFIREG Pesticide Meeting.** At the request of EPA Region 6 staff, CWPB participated via conference call in the State/Tribal pre-SFIREG meeting on October 7. CWPB presented information on EPA's proposed rule revisions to the Worker Protection Standard (WPS) and Certification of Pesticide Applicators (C&T) rules. CWPB staff provided information about the proposals being considered in EPA's pending revision of the C&T rule and also provided an update on the status of the WPS proposed rule and the nature of the comments received to date in response to the publication of the WPS notice of proposed rulemaking. (Richard Pont, 305-6448)

**FEAD Continues Participation in National PSEP Improvement & Modernization Initiative.** The National Pesticide Safety Education Program Improvement and Modernization Initiative (PSEP-IMI) is a 3-year initiative to enhance stability and sustainability of the PSEP program and improve the education of pesticide applicators. CWPB staff participate on biweekly conference calls with the PSEP-IMI Board of Directors that oversees the PSEP-IMI effort that has been funded through contributions from pesticide registrants who have committed to providing approximately \$1 million a year for the next 3 years to support the PSEP-IMI effort. To date, 25 state PSEPs have already been awarded grant funding to pursue the 3-year effort of building self-sustaining PSEPs. Another 10 have received funding to pursue other C&T-related projects such as development of needed national training materials or development of regional websites that will compile information on quality C&T materials and resources that have been developed so PSEPs will have a centralized location to go to access information on the range of C&T materials that are available nationally in order to reduce duplication and improve sharing among PSEPs. EPA provides technical support. (Richard Pont, 305-6448)

## INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

**ITRMD's Information Technology (IT) Staff Participate in Important Training:** Several staff from ITRMD attended a three day workshop focusing on Information Technology Infrastructure Library (ITIL). ITIL is a framework that focus on identifying, planning, delivering, and supporting IT services to the organization. The discipline describes processes, procedures, tasks, and checklists which are not OPP specific, but can be applied by ITRMD to establish integration with OPP's strategy, delivering value, and maintaining level of competency as we plan the IT infrastructure and systems more effectively. This foundational course will allow ITRMD to establish a baseline from which it can plan, implement, and measure. (Hamaad Syed, 703-305-0502)



 <b>OPP FOIA Request Status Report for Sept 29- Oct. 3, 2014</b> 							
Requests Received		Requests Closed			Requests Open		
FY15	This Week	FY15	FYTD	This Week	FY15	Prior Years	Total
3	8	0	44	44	3	341	344

(Ana Espinoza, 703-347-0102)

## BIOPESTICIDES & POLLUTION PREVENTION DIVISION

**Meeting On Respiratory Sensitization Proposal** On October 8, HED (Jeff Dawson) and BPPD (John Leahy) met with Curt Lunchick with Bayer Crop Science to discuss a proposal to develop a respiratory sensitization test for microbial pesticide active ingredients. The proposed test may provide adequate information to determine reliably whether a microbial pesticide causes respiratory sensitization. If it does not, EPA may be able to allow a reduction in label requirements for respiratory protection. OPP scientists are reviewing the proposal and plan to provide feedback within a few weeks. (John Leahy, 305-6703; Jeff Dawson, 305-7329)

## ENVIRONMENTAL FATE & EFFECTS DIVISION

### **OPP Staff Brief the Honey Bee Health Coalition on OPP Incident Workgroup**

**Activities.** On Oct. 3, the OPP Incident Workgroup provided an overview of their current activities to the Honey Bee Health Coalition via a webinar. The Honey Bee Health Coalition (HBHC) was convened by the Keystone Center to improve the health of honey bees and other pollinators and is made up of beekeepers, growers, researchers, government agencies, conservation groups, registrants and other stakeholders. One of the goals of the HBHC is to improve pesticide incident reporting. The webinar included an overview of the importance of incident data that was followed by a description of the current OPP Incident Workgroup's vision, goals, and future projects. Many of the incident workgroup's future projects will involve opportunities for stakeholder involvement, and the HBHC expressed interest in participating in those efforts (Melissa Panger, 703-305-6136; Rich Dumas, 703-308-8015).

### **EPA, FWS, NMFS, and USDA Host Third Stakeholder Workshop on Interim Scientific Approaches to NAS Report Recommendations.**

On October 6, 2014, EPA, the U.S. Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the U.S. Department of Agriculture (USDA) held a third workshop for stakeholders to offer scientific and technical feedback on the joint inter-agency interim scientific approaches issued in November 2013 in response to the National

Academy of Sciences (NAS) report entitled, "Assessing Risks to Endangered and Threatened Species from Pesticides." The workshop was attended by registrants, environmental consultants, and NGOs, including the Center for Biological Diversity and the Center for Food Safety. The workshop format was interactive with morning presentations from FWS on the initiative to obtain listed species range maps and from EPA on the status of the interagency work on the three pilot chemicals (malathion, chlorpyrifos, and diazinon) to further develop the interim scientific approaches based on the NAS report recommendations. In the afternoon session, stakeholders presented on the role of multiple species and crop attributes in understanding the potential for exposure, characterization of uncertainty in EFED's aquatic risk assessments, probabilistic methods, and weight-of-evidence analysis. There was significant interest in potential changes to current methods for modeling aquatic exposure, refinements to reduce the number of species for which consultation is required, the timeline for completion of draft biological evaluations for the three pilot chemicals, and associated decisions relative to modeling, use of probabilistic methods, and weight-of-evidence analysis. The agencies will consider the information provided at the workshop as part of the ongoing work to further develop the scientific methods for evaluating the potential risks of pesticides to listed species. (Anita Pease, 703-305-0392).

## HEALTH EFFECTS DIVISION

**HED and PRD Interviewed by Office of the Science Advisor on the Topic of Cumulative Risk Assessment (CRA) Methods at OPP:** Members of HED (Elissa Reaves, Billy Smith, and Dana Vogel) and PRD (Mike Goodis) were interviewed by members of the Office of the Science Advisor (OSA) on the topic of CRA methods at OPP. OSA is collecting information on the CRA experience and methods of the various different programs within EPA. This information will be used going forward to help shape the efforts of the Risk Assessment Forum in producing agency CRA guidelines. HED and PRD provided information in the interview related to the methods around common mechanism of toxicity, exposure assessment, and risk mitigation strategies. (Billy Smith, 305-0291)

**Meeting to Discuss New Picaridin Product:** Representatives from HED, PRD, and RD met with the registrant for picaridin to discuss the status and data requirements for a new dog and walker repellent product. The main discussion topics were related to the efficacy data and a required companion animal safety study, which the registrant would like to satisfy using a chronic dermal study in the dog. The Agency suggested that the registrant formally submit justification as to why the dog toxicity study will adequately fulfill the requirement for the companion study. (Karlyn Middleton, 308-0004)

**US Comments Sent on Draft OECD Test Guideline:** Zaida Figueroa and Christine Olinger, US National Coordinator for the OECD Test Guideline Program, compiled

US comments on a draft OECD test guideline: "Reconstructed Human Cornea Epithelium Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage." This is an alternative method to the *in vivo* method for testing eye irritation. Comments were received from two FDA offices. This test guideline is slated for approval at the annual meeting of National Coordinators in April 2015. (Christine Olinger, 305-5147)

**AHETF Joint Regulatory Committee (JRC) Meeting and OD Briefing:** On October 8<sup>th</sup>, AHETF (Agricultural Handlers Exposure Task Force) briefed the office director and several division directors on their current status, future plans, current policy issues, and international use of their data. Following the briefing, HED staff participated in a meeting with the JRC of the AHETF. Staff from California DPR and Canada's PMRA also participated. Several topics were considered including: the development of unit exposure estimates for right of way spraying operations; the upcoming HSRB meeting in November on the submitted granular loading protocol; remaining scenarios where field work is still ongoing, review of submitted monographs (e.g., seed treatment); and how the hand wash efficiency issue should be addressed. (Jeff Dawson, 305-7329; Jeff Evans, 305-7877)

**Propylene Oxide (PPO) Team Meets with Registrant on DCIs Issued in Registration Review:** The HED/RAB4 risk assessment team met with Balchem/ABERCO to discuss the need for additional exposure and toxicity studies requested as part of Registration Review. PPO is a spice and structural fumigant. Based on the discussion at the meeting, the registrant is planning to submit exposure and modeling data to the agency demonstrating de minimus exposure to workers and bystanders from the spice and structural fumigation use pattern, thus negating the need for more data. (Elissa Reaves, 305-0312)

**OPP Representatives Meet with Commercial Real Estate Developer:** Members from HED (Jeff Dawson, Matt Lloyd), PRD, and BEAD met with a commercial real estate developer interested in researching advanced methyl bromide capture systems. The developer was interested in designing and developing an indoor cold storage facility for perishables arriving at the port of Charleston, South Carolina. OPP staff provided some references and considerations for the developer including: 1) investigating the upcoming MBAO meeting; 2) contacts for EPA's air office to consider air permitting requirements; 3) potential contacts from the fumigation community; and 3) background information on upcoming methyl bromide label changes. (Matt Lloyd, 308-0130)



## REGISTRATION DIVISION

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
<b>The Fungicide Branch granted:</b>					
Tetraconazole	Sipcam Agro USA, Inc.	60063-11	R351	10/14/2014	10/7/2014
<b>Marcel Howard, 703/305-6784</b>					
Paclobutrazol	Fine AgroChemicals, Ltd.	62097-24	R352	10/27/2014	10/7/2014
<b>Lindsay Roe, 703/347-0506</b>					
<b>The Herbicide Branch granted:</b>					
Dicamba, sodium salt	Albaugh, LLC	42750-271	R310	11/20/2014	10/7/2014
<b>Shanta Adeeb, 703/347-0502</b>					
Chlorimuron	Sharda CropChem Limited	82633-22	R333	10/20/2014	10/7/2014
<b>Mindy Ondish, 703/605-0723</b>					
Bromoxynil octanoate	Bayer CropScience LP	264-1023 264-1135	R350	10/8/2014	10/7/2014
Mesosulfuron-methyl	264-802	R350	R350	10/8/2014	10/7/2014
<b>Bethany Benbow, 703/347-8072</b>					
<b>The Insecticide Branch granted:R340</b>					
Piperonyl butoxide	Ultrason Industries Limited	73804-2	R300	10/7/2014	10/3/2014
<b>Carmen Rodia, 703/306-0327</b>					
Permethrin	Repar Corporation	69361-45 69361-46	R300	10/10/2014	10/7/2014
<b>Driss Benmhend, 703/308-9525</b>					
<b>The Insecticide-Rodenticide Branch granted:</b>					
Diphacinone	Hacco, Inc.	61282-63	R300	1/20/2015	10/6/2014
Imidacloprid	NuFarm Americas, Inc.	228-572	R340	12/15/2014	10/7/2014
<b>Gene Benbow, 703/347-0235</b>					
<b>PRIA Categories</b>					
<p><b>R300</b> – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix <a href="#">(3)</a> <a href="#">(4)</a>; <b>R310</b> – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging <a href="#">(2)</a> <a href="#">(3)</a>; <b>R333</b> – New product; MUP or End use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. <a href="#">(2)</a> <a href="#">(3)</a>; <b>R340</b> – Amendment requiring data review within RD (e.g., changes to precautionary label statements) <a href="#">(2)</a> <a href="#">(3)</a>; <b>R350</b> – Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) <a href="#">(2)</a> <a href="#">(3)</a>; <b>R351</b> – Amendment adding a new unregistered source of active ingredient <a href="#">(2)</a> <a href="#">(3)</a>; and <b>R352</b> – Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data <a href="#">(2)</a> <a href="#">(3)</a>.</p>					